Study of MGY825 in Patients With Advanced Non-small Cell Lung Cancer

Last Update: Apr 23, 2025
An Open-label, Phase I, Dose Escalation, Expansion Study of MGY825 in Adult Patients With Advanced Non-small Cell Lung Cancer
ClinicalTrials.gov Identifier:
NCT05275868
Novartis Reference Number:CMGY825A12101
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All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

Study of MGY825 single agent in adult patients with advanced non-small cell lung cancer. First in human, phase I, multicenter, open-label study of MGY825 single agent with a dose escalation and a dose expansion in adult patients with advanced non-small cell lung cancer (NSCLC).

The dose escalation part will investigate the safety and tolerability of MGY825 in adult patients with advanced NSCLC harboring NFE2L2, or KEAP1 or CUL3 (NFE2L2/KEAP1/CUL3) mutations. Patient enrollment will be based on locally available test results of mutation status.

An exploratory assessment on the effect of food may be investigated during the dose escalation part.

The dose expansion part will assess the preliminary anti-tumor activity and further assess the safety and tolerability of MGY825 in adult patients with advanced NSCLC divided in two patient groups.

Group 1: Patients with advanced NSCLC harboring NFE2L2/KEAP1/CUL3 mutations enrolled based on locally available test results of mutation status.

Group 2: Patients with advanced NSCLC irrespective of prior knowledge of NFE2L2/KEAP1/CUL3 mutational status.

Condition
Non-small Cell Lung Cancer
Phase
Phase1
Overall Status
Recruiting
Number of Participants
140
Start Date
Oct 05, 2022
Completion Date

Jul 28, 2027
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

MGY825

investigational drug

Eligibility Criteria

Inclusion Criteria:

* Signed informed consent must be obtained prior to participation in the study.
* Dose escalation and dose expansion group 1:

Patients with histologically or cytologically confirmed diagnosis of advanced (metastatic or unresectable) NFE2L2/KEAP1/CUL3 mutant NSCLC. Local data confirming the NFE2L2/KEAP1/CUL3 mutation status in tissue must be available for enrollment.

* Dose expansion group 2:

Patients with histologically or cytologically confirmed diagnosis of advanced (metastatic or unresectable) NSCLC irrespective of NFE2L2/KEAP1/CUL3 mutation status.

* All patients:

Patients must have progressed after 1 platinum-based chemotherapy regimen and PD-(L)1 antibody therapy either sequentially or concurrent with chemotherapy, where indicated, for Stage IV NSCLC.

Patients treated with neo-adjuvant / adjuvant platinum-based therapy that progressed within 6 months of treatment are permitted to participate.

Prior therapy with VEGF/VEGFR targeting agents is permitted. Prior treatment with approved targeted drugs (e.g., EGFRi, ALKi, METi) is mandatory in patients with NSCLC whose tumor bears actionable mutations.

* Presence of at least one measurable lesion according to RECIST v1.1.
* Patient must have a site of disease amenable to biopsy and be a candidate for tumor biopsy according to the treating institution's guidelines. Patient must be willing to undergo a new tumor biopsy at screening and during study treatment. A recent biopsy collected after the last systemic treatment and within 3 months before study entry may be submitted at screening.

Exclusion Criteria:

* Having out of range laboratory values defined as:

Creatinine clearance (calculated using Cockcroft-Gault formula, or measured) \< 60 mL/min Total bilirubin \>

1.5 x ULN, except for patients with Gilbert's syndrome who are excluded if total bilirubin \> 3.0 x ULN or direct bilirubin \> 1.5 x ULN ALT \> 3 x ULN AST \> 3 x ULN ANC \< 1.0 x 109/L Platelet count \< 75 x 109/L Hemoglobin \< 9 g/dL

* Impaired cardiac function or clinically significant cardiac disease, including any of the following:

Clinically significant and/or uncontrolled heart disease such as congestive heart failure requiring treatment (NYHA Grade ≥2), uncontrolled hypertension or clinically significant arrhythmia.

QTcF \> 470 msec on screening ECG or congenital long QT syndrome. Acute myocardial infarction or unstable angina pectoris \< 3 months prior to study entry.

* Presence of symptomatic CNS metastases, or CNS metastases that require local CNS-directed therapy (such as radiotherapy or surgery) or increasing doses of corticosteroids within 2 weeks prior to study entry. Patients with treated symptomatic brain metastases should be neurologically stable (for 4 weeks post-treatment and prior to study entry) and at a dose of ≤ 10 mg per day prednisone or equivalent for at least 2 weeks before administration of any study treatment.
* Known active COVID-19 infection.
* Unable or unwilling to swallow capsules as per dosing schedule. Other protocol-defined inclusion/exclusion criteria may apply.

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